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Attention: (8e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

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Ladies and Gentlemen:

Subject: Notice in Accordance to TSCA Section 8(e) - Preliminary results of a range-finding reproduction toxicity study in Wistar rats with a developmental fungicide.

BASF Corporation is submitting the preliminary results of a range-finding reproduction toxicity study with a developmental fungicide. The study was conducted by our parent company, BASF Aktiengesellschaft, Ludwigshafen, Germany.

The test substance with the name substituted benzylether is a developmental fungicide. Small shipments totaling approximately 1.3 kg active ingredient have been shipped since 1993.

This range-finding study was carried out in accordance with OECD Guideline 415 "One Generation Reproduction Toxicity Study" (1983). The test substance was administered via the diet to 10 Wistar rats per sex and group at dose levels of 0; 1,500, 3,000 and 4,500 ppm. About 6 weeks after beginning of treatment, the (F0) animals were mated to produce a (F1) litter. The pups were raised until day 4 (standardization of litters) or day 21 after birth. Thereafter the study was terminated by the terminal sacrifice of F1 weanlings and F0 adult animals.

The following is a summary of the most relevant findings:

In this study, clear dose-dependent signs of general toxicity in the parental animals occurred at 1,500, 3,000 and 4,500 ppm; this was substantiated by reduced food consumption, impairments in body weight gain, impaired clinical pathology and hematology as well as gross pathological findings.

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Signs of developmental toxicity in the form of lower mean number of delivered pups/litter and increased pup mortality at the top dose only as well as significantly lower pup body weights/impaired body weight gains were observed at and above 1,500 ppm. Furthermore, gross pathological findings (dilatation of hearts and discoloration of livers) were recorded in the pups at all dose levels. However, these findings showed no dose-response relationship.

Although the signs of developmental toxicity noted in the present, range-finding reproduction toxicity study appeared only in the presence of parental toxicity, BASF Corporation understands that the reporting of these study results is in accordance with EPA's policy.

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All persons handling or testing this developmental product will be notified of these preliminary results via an updated Material Safety Data Sheet. Any reports or additional information that we receive will be forwarded to the Agency.

If you have any questions, please feel free to call me at (734) 324-6207.

Very Truly Yours,

BASF Corporation

Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations